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PNEUMOCOCCAL VACCINE TO COUNTER EMERGING INFECTIOUS DISEASE THREAT IN THE MILITARY

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Report No. 00-36

Approved for public release; distribution unlimited.

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Pneumococcal Vaccine to Counter Emerging Infectious Disease Threat in the Military

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***Streptococcus pneumoniae* causes severe morbidity and mortality worldwide and poses a significant threat to the health and readiness of U.S. military personnel. Although a vaccine to prevent pneumococcal infections has been available for almost 25 years, its use has been limited. Recently, increasing antibiotic resistance among *S. pneumoniae* strains has emerged, prompting health care professionals to reevaluate the benefit of administering pneumococcal vaccine. The Naval Health Research Center, in collaboration with professionals from numerous civilian and military organizations, has initiated a rigorous double-blind, placebo-controlled trial investigating the operational value of vaccinating young adults as they enlist in the military.**

Introduction

Diseases caused by *Streptococcus pneumoniae* (the pneumococcus) are associated with tremendous morbidity and mortality worldwide, and they are a special threat to the health and readiness of the U.S. military. A vaccine to prevent pneumococcal disease has been available for clinical use in the United States for nearly 25 years. Vaccination has been strongly recommended for the elderly, and recently, for very young children, yet its utility in young adults has not been well examined. As a result of recent outbreaks of pneumococcal disease and the emergence of increased antibiotic resistance, a large clinical trial of pneumococcal vaccine among young adults enlisting in the U.S. military is currently being undertaken by the Naval Health Research Center, in San Diego, in collaboration with public health, academic, and military institutions. The study will better define the burden of pneumococcal disease in U.S. military populations and the value of vaccination in protecting healthy young adults.

Pneumococcal Disease

S. pneumoniae are Gram-positive, usually encapsulated cocci that occur singly, in pairs, or in short chains. Of the more than 90 serotypes of *S. pneumoniae*, types 1, 3, 4, 7, 8, 9, 12, 14, and 23F are the most common causes of infection among adults.[1-3] Pneumococci are responsible for a broad spectrum of human disease, ranging from otitis media, mastoiditis, and sinusitis to invasive disease such as pneumonia, meningitis, and sepsis. Some populations are more vulnerable to severe pneumococcal disease, including immunocompromised patients, those with functional or anatomic asplenia, the very old, the very young, and Native American, Native Alaskan, and African-American populations.[4] All risk factors are not well defined, however, because otherwise healthy young adults can also suffer from invasive pneumococcal disease.

For nearly two centuries, invasive pneumococcal disease, especially pneumonia, has been recognized as a common and often critical condition.[5] The pneumococcus continues to rank among the leading causes of death from infectious disease worldwide,[6-8] and it remains a significant cause of morbidity and mortality in the United States.[9] Each year, the pneumococcus is estimated to cause approximately 500,000 cases of pneumonia, 50,000 cases of bacteremia, and 3,000 cases of meningitis in this country.[3] Surveillance for pneumococcal infections in Soweto, South Africa, and Papua New Guinea reveal that the pathogen is an even greater threat to some subpopulations in those areas.[10,11]

In addition to the impact *S. pneumoniae* has had on civilian populations, it has also challenged the health and readiness of the U.S. military population. Navy data from 1981 to 1991 suggest that the pneumococcus has been responsible for 12% of military pneumonia hospitalizations, or 9.5 admissions per 100,000 person-years.[12] During the winter of 1989, an epidemic of at least 124 cases of confirmed pneumococcal pneumonia occurred at Camp Pendleton, California,[12] affecting troop readiness and placing a strain on medical resources. Other outbreaks have been documented in the military in North Carolina and on a ship in the Mediterranean Sea.[13] Most recently, 56 Marine Corps recruits were hospitalized, and many more were treated as outpatients, during an outbreak of pneumococcal pneumonia at Camp Pendleton during the winter of 2000 (CDR Kenneth Earhart, Naval Medical Center, San Diego, personal communication). It is suspected that many more military mem-

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This research is being conducted in compliance with all applicable federal regulations governing the protection of human subjects in research under Department of Defense protocol 31256.

The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, the Department of Defense, or the U.S. Government.

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This manuscript was received for review in November 2000. The revised manuscript was accepted for publication in June 2001.

bers are affected by pneumococcal disease; however, because of diagnostic difficulties in identifying *S. pneumoniae*, the true incidence is unknown.[13]

Since the 1940s, the preferred method of treatment for pneumococcal infections has been a regimen of antibiotics.[5,8,14] Penicillins, cephalosporins, and fluoroquinolones have all been used to successfully treat *S. pneumoniae* disease.[15,16] Unfortunately, the widespread use of antibiotics led to the emergence of antibiotic-resistant strains of *S. pneumoniae* in the 1980s. Today, even the most recently introduced antibiotics, such as fluoroquinolones, show signs of decreased effectiveness against the pneumococcus.[16,17] Recent research identifies penicillin-resistant strains of *S. pneumoniae* as the most prevalent.[17–19] One study documented an increase in the incidence of penicillin-resistant pneumococci in a pediatric population from 0% in 1990 to 36.2% in 1994.[19] Another study found that 55% of *S. pneumoniae* isolates were resistant to penicillin. These penicillin-resistant isolates were most commonly serotypes 6A, 6B, 14, 19F, 23F, and nontypable.[17] Four of these serotypes are found in the 23-valent pneumococcal vaccine.

Antibiotic resistance is a special concern within the military, in which benzathine penicillin G has been used prophylactically since 1953 to prevent group A streptococcal disease in high-risk settings. Although current data do not suggest that the use of benzathine penicillin G has contributed to resistant *S. pneumoniae* strains,[20] the military must remain vigilant for this possibility.

Strains of *S. pneumoniae* with resistance to penicillin and other drugs pose new challenges in the treatment of pneumococcal infections,[21] and they underscore the importance of using measures to limit the propagation of resistant strains.[22,23] As antibiotic-resistant pneumococci become a greater threat worldwide, the use of primary prevention, in the form of pneumococcal vaccine, is expected to become more critical.[3,22–28]

Pneumococcal Vaccine

In 1945, the first successful trial of a polyvalent polysaccharide vaccine against pneumococcal pneumonia was completed by MacLeod and collaborators.[29] After the advent of penicillin therapy for treatment, interest in the vaccine seemed to wane. It was not until 1977 that a 14-valent vaccine was finally approved for clinical use in the United States. In 1983, the manufacturer expanded the formulation, creating a 23-valent vaccine.[30] This 23-valent polysaccharide vaccine has since been recommended for the prevention of invasive pneumococcal disease in high-risk groups, including people with chronic illness, asplenia, immune compromise, or age older than 65 years.[5,31]

Recommendations for more widespread use of pneumococcal vaccine have grown in recent years. In 1997, the Immunization Practices Advisory Committee of the Centers for Disease Control and Prevention updated its recommendations to include vaccination of people between the ages of 2 and 64 years who are living in settings where the risk for pneumococcal infection is increased, such as certain Native American populations.[32] Most recently, the first conjugate pneumococcal vaccine, designed specifically for infants and children, was licensed by the Food and Drug Administration and is now recommended for general pediatric use.[33,34] In 1998, the Armed Forces Epidemiological Board[35] recommended that the 23-valent vaccine be evaluated for use in high-risk military populations. Thus far, only one recruit training camp and some elite military groups (Navy SEALs and Army Rangers) have opted to provide vaccine for their trainees. The efficacy of the pneumococcal vaccine in these military populations has not been established.

Despite the 23-valent vaccine's long history and expanding recommendations for use, some authors have noted conflicting evidence on the vaccine's efficacy.[31] Although some studies of pneumococcal polysaccharide vaccine show an overall protective efficacy of about 60 to 70%,[36] studies in immunocompromised patients have shown much lower levels of protection.[31] Persons suffering from various states of immunodeficiency do not consistently develop immunity after vaccination, thus reducing the protective value of the vaccine. However, in the healthy elderly population (immunocompetent persons older than 65 years), the polysaccharide vaccine has a reported efficacy of 75%.[23,36] The 23-valent vaccine has also been shown to be effective in preventing bacteremia in all groups older than 2 years studied to date. The efficacy of the conjugate 7-valent vaccine in children appears to also be high, at >80% for preventing invasive disease.[37]

The cost effectiveness of the vaccine appears to have been established among high-risk populations by some researchers,[32,38–41] although other data suggest that the cost effectiveness may still be in question.[42–45] It has been proposed that large, rigorous trials investigating the safety, efficacy, and cost effectiveness of the pneumococcal vaccine are necessary before widespread use of the vaccine should be advocated.[30]

New Vaccine Research in the Military

The Naval Health Research Center, in collaboration with professionals from the Centers for Disease Control and Prevention, the Mayo Clinic and Foundation, Wyeth Lederle Vaccines, and a number of military commands, will soon be initiating a large double-blind, placebo-controlled clinical trial of the currently available 23-valent pneumococcal vaccine. The purpose of this study is to determine the operational benefit of vaccinating young adults as they enlist in the military. This $3 million study has been made possible through a competitive research grant administered by the U.S. Army Medical Research and Material Command and a Cooperative Research and Development Agreement with Wyeth Lederle Vaccines.

A population of more than 191,000 Army, Navy, and Marine Corps recruits will be enrolled in the vaccine trial, actively followed during their 8 to 12 weeks of recruit training, and passively followed for respiratory disease outcomes for up to 15 months after training. Four recruit training facilities originally agreed to participate in this operationally complex study. These training facilities—the Marine Corps Recruit Depot, San Diego, California; Navy Recruit Training Command, Great Lakes, Illinois; and Army basic combat training facilities at Fort Leonard Wood, Missouri, and Fort Jackson, South Carolina—have each agreed to take on the challenge of executing this important study with minimal disruption to established training schedules (Fig. 1). The Marine Corps Recruit Depot, at Parris Island, South Carolina, will be added to the group of participating facilities within the year.

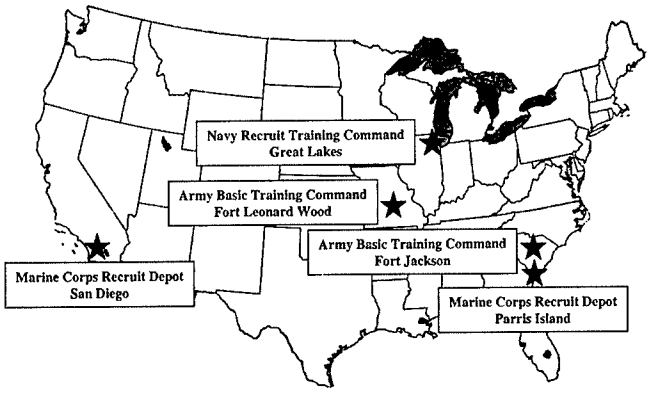

Fig. 1. Pneumococcal vaccine study sites.

Recruits will be offered participation in the study from October 2000 through February 2002. Consenting participants will be randomly assigned to receive either pneumococcal vaccine or a placebo injection during routine medical in-processing. All recruits will be followed closely for pneumonia during basic training, and they will receive extensive medical evaluations should they become ill. Laboratory workups will identify infection with *S. pneumoniae*, with serotyping and antibiotic-resistance, as well as the burden of other pathogens (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, adenovirus, influenza, and respiratory syncytial virus) among recruit pneumonia cases. Time lost from training will be carefully tracked among recruits enrolled in this study.

After basic training, computerized medical data containing International Classification of Diseases, Ninth Revision, diagnostic codes for any-cause pneumonia and any-cause acute respiratory disease (codes 460–466 and 480–487) will be tracked for the study group for up to 15 months. Hospitalizations at military medical facilities will be identified using the Standard Inpatient Data Records system. Figure 2 shows the incidence of such hospitalizations from 1997 to 1999. Outpatient encounters at Department of Defense facilities will be identified using the Standard Ambulatory Data Records system, which has only available in the past few years. Data analysts at the Naval Health Research Center have established direct access to these large databases to thoroughly capture all respiratory illness encounters recorded among study participants. These health care databases are robust and standardized. Although identification of pneumococcal disease through these systems may be imperfect, the results will be unbiased because of the randomization procedure performed at study enrollment.

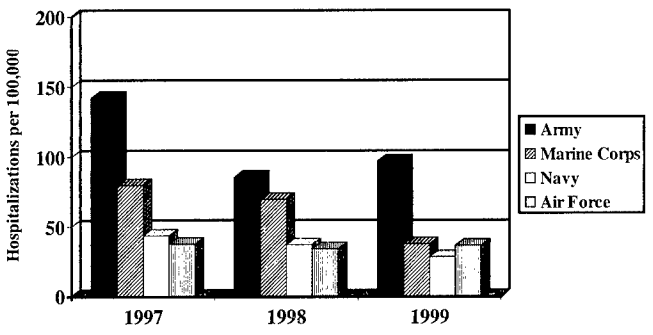

Fig. 2. Rates of hospitalizations for respiratory illness (International Classification of Diseases, Ninth Revision, codes 460–466 and 480–487) per 100,000 junior enlisted personnel (E1–E3) by service branch, January 1997 to December 1999.

This large vaccine trial will reveal the clinical value of using pneumococcal vaccine in military recruits. Sophisticated laboratory data on *S. pneumoniae* will be closely linked to health care utilization and lost training time to demonstrate the effects on health and readiness that are critical to the Department of Defense. This study received an excellent scientific merit score by the American Institute of Biological Sciences,[46] and it is anticipated to be followed closely by civilian public health officials. The research may prompt new recommendations for the use of pneumococcal vaccine in other young adult populations, including high school and college students, health care workers, other public service occupations, and foreign military groups.[12,47,48]

Conclusion

S. pneumoniae is a significant cause of illness in the United States and around the world. In addition to its impact on the health of civilians, the pneumococcus, with its increasing resistance to antibiotics, threatens to compromise the readiness of U.S. military forces. Although an available vaccine against pneumococcal infections might help to reduce this impact, vaccination has not been well studied in healthy young adults without other risk factors. This pneumococcal vaccine study will be one of the largest double-blind, placebo-controlled clinical trials in U.S. military history. This operational research is expected to provide critical information to military policymakers and to have additional value for civilian public health professionals.

Acknowledgment

This represents Naval Health Research Center report 00-36, supported by the Department of the Navy, under research work unit 0H8086-6609.

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REPORT DOCUMENTATION PAGE

1. Report Date (DD MM YY)	2. Report Type	3. DATES COVERED (from - to)
8-24-00	New	Aug 2000

4. TITLE AND SUBTITLE
Pneumococcal Vaccine to Counter Emerging Infectious Disease Threat in the Military

5a. Contract Number:
5b. Grant Number:
5c. Program Element: 61102A
5d. Project Number: M0101
5e. Task Number: BKX
5f. Work Unit Number: **6609**

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P.O. Box 85122
San Diego, CA 92186-5122

8. PERFORMING ORGANIZATION REPORT NUMBER
Report No. 00-36

8. SPONSORING/MONITORING AGENCY NAMES(S) AND ADDRESS(ES)
Chief, Bureau of Medicine and Surgery
Code M2
2300 E St NW
Washington DC 20372-5300

10. Sponsor/Monitor's Acronyms(s)
BUMED

11. Sponsor/Monitor's Report Number(s)

12 DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES
Published in: Military Medicine, 2001, 166(12), 1089-90

14. ABSTRACT (maximum 200 words)

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14. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	18a. NAME OF RESPONSIBLE PERSON
a. REPORT	b.ABSTRACT	b. THIS PAGE			Commanding Officer
UNCL	UNCL	UNCL	UNCL	4	18b. TELEPHONE NUMBER (INCLUDING AREA CODE) COMM/DSN: (619) 553-8429